

vember 26, 2014, except as otherwise provided in this part.

(2) Ensuring safety and effectiveness

Nothing in this part shall be construed to alter the authority of the Secretary with respect to prohibiting the marketing of a sunscreen that is not safe and effective or is misbranded, or with respect to imposing restrictions on the marketing of a sunscreen to ensure safety and effectiveness, except as otherwise provided in this part, including section 360fff-3(e) of this title.

(3) Other drugs

Except as otherwise provided in section 360fff-6 of this title, nothing in this part shall be construed to affect the authority of the Secretary under this chapter or the Public Health Service Act (42 U.S.C. 201 et seq.) with respect to a drug other than a nonprescription sunscreen.

(4) Effect on drugs otherwise approved

Nothing in this part shall affect the marketing of a drug approved under section 355 of this title or section 351 of the Public Health Service Act [42 U.S.C. 262].

(c) Timelines

The timelines for the processes and procedures under paragraphs (1), (2), (5), and (6) of section 360fff-3(a) of this title shall not apply to any requests submitted to the Secretary under section 360fff-1 of this title after the date that is 6 years after November 26, 2014.

(June 25, 1938, ch. 675, §586D, as added Pub. L. 113-195, §2(a), Nov. 26, 2014, 128 Stat. 2044.)

REFERENCES IN TEXT

The Public Health Service Act, referred to in subsec. (b)(3), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

§ 360fff-5. Sunscreen monograph

(a) In general

Not later than 5 years after November 26, 2014, the Secretary shall amend and finalize regulations under part 352 of title 21, Code of Federal Regulations concerning nonprescription sunscreen that are effective not later than 5 years after November 26, 2014. The Secretary shall publish such regulations not less than 30 calendar days before the effective date of such regulations.

(b) Reports

If the regulations promulgated under subsection (a) do not include provisions related to the effectiveness of various sun protection factor levels, and do not address all dosage forms known to the Secretary to be used in sunscreens marketed in the United States without a new drug approval under section 355 of this title, the Secretary shall submit a report to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives on the rationale for such provisions not being in-

cluded in such regulations, and a plan and timeline to compile any information necessary to address such provisions through final regulations.

(June 25, 1938, ch. 675, §586E, as added Pub. L. 113-195, §2(a), Nov. 26, 2014, 128 Stat. 2045.)

§ 360fff-6. Non-sunscreen time and extent applications

(a) Pending time and extent applications

(1) In general

(A) Request for framework for review

If, prior to November 26, 2014, an application was submitted pursuant to section 330.14 of title 21, Code of Federal Regulations for a GRASE determination for a drug other than a nonprescription sunscreen active ingredient or combination of nonprescription sunscreen active ingredients and such drug was found to be eligible to be considered for inclusion in the over-the-counter drug monograph system pursuant to section 330.14 of title 21, Code of Federal Regulations, the sponsor of such application may request that the Secretary provide a framework under paragraph (2) for the review of such application.

(B) Request requirements

A request for a framework for review of an application made under subparagraph (A) shall be made within 180 calendar days of November 26, 2014, and shall include the preference of such sponsor as to whether such application is reviewed by the Secretary in accordance with—

(i) the processes and procedures set forth for pending requests under section 360fff-3(b) of this title, except that specific timelines shall be determined in accordance with other applicable requirements under this section;

(ii) the processes and procedures set forth under part 330 of title 21, Code of Federal Regulations (or any successor regulations);

(iii) an initial filing determination under the processes and procedures described in section 360fff-2(b) of this title and the processes and procedures set forth for pending requests under section 360fff-3(b) of this title, except that specific timelines shall be determined in accordance with other applicable requirements under this section; or

(iv) an initial filing determination under the processes and procedures described in section 360fff-2(b) of this title and the processes and procedures set forth under part 330 of title 21, Code of Federal Regulations (or any successor regulations).

(C) No request

If a sponsor described in subparagraph (A) does not make such request within 180 calendar days of November 26, 2014, such application shall be reviewed by the Secretary in accordance with the timelines of the applicable regulations when such regulations are finalized under subsection (b).